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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,098	10/14/2004	Akira Ideno	Q83564	9139
23373 7590 08/20/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
PROUTY, REBECCA E				
ART UNIT		PAPER NUMBER		
1652				
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08/20/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,098

Applicant(s)

IDENO ET AL.

Examiner

Rebecca E. Prouty

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2008 and 20 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-39 and 41-64 is/are pending in the application.
- 4a) Of the above claim(s) 38, 39, 43-52, 57 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-37, 41, 42, 53-56 and 59-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/08, 7/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claims 1-32 and 40 have been canceled. Claims 33-39 and 41-64 are at issue and are present for examination.

Claims 38, 39, 43-52 and 57-58 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/23/07.

Claim 35 is confusing in the recitation of "encodes a protease digestion site in the same reading frame as (a) and (b)" as (b) of the expression vector of claim 33 does not include a coding region but merely a restriction site into which a second coding region may be inserted. It is suggested that "in the same reading frame as (a) and (b)" be replaced with "in the same reading frame as (a)".

Claim 61 is unclear in the recitation of "a signal sequence at ... a 3' terminus of the second coding region" as signal sequences which provide for export into the periplasm or media when fused at the 3' terminus of a protein coding sequence are not known in the art. Applicants remarks state that Claim 61 has been amended to correct a typographical error to recite "a 5' terminus of the second coding region of the expression vector." however no such amendment has been made. Furthermore, even if the claim were amended as such this would be confusing

as signal sequences which provide for export into the periplasm or media when within the interior of a protein (i.e., between the PPIase domain and the desired protein domain of the fusion protein) are not known in the art either.

Claim 61 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as filed does not provide support for the recitation of "a signal sequence at ... a 3' terminus of the second coding region". As stated above applicants state that this language has been amended to recite "a 5' terminus of the second coding region of the expression vector." which has support on pages 6 and 27 of the original specification however no such amendment has been made.

The rejections of the claims under 112, first paragraph (except for the rejection of claim 55 below) are withdrawn in view of the amendment of the claims to be limited to archaeobacterial FKBP-type PPIases, i.e., naturally occurring

PPIases for which the art provides several representative species all having known similar structural features.

Claim 55 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated host cell transformed with the recited expression vector, does not reasonably provide enablement for host cells within a multicellular organism that have been transformed with the recited expression vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection is explained in the previous Office Action.

Applicants appear to believe that the amendment of claim 55 to recite that the host is selected from the group consisting of a bacterium, a yeast, a fungus, a plant, an insect cell, and a mammalian cell will overcome the instant rejection. However, as there is no limitation that the plant, insect or mammalian cells recited cannot be within a multicellular plant, insect or mammal, the instant amendment does not overcome the rejections. It is suggested that the claim be amended to recite "An isolated host cell ...".

The rejection of the claims under 102 over Scholz et al. (US PG-PUB 2003/0096352) is withdrawn in view of the amendment of the claims to be limited to archaeobacterial FKBP-type PPIases

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33-37, 41-42, 53-56, and 59-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fersht (WO 00/75346) in view of Furutani et al. The rejection is explained in the previous Office Action.

Applicants argue that Fersht does not teach or suggest the presently claimed expression vector wherein the PPIase having molecular chaperone activity is archaeobacterial FKBP-type PPIase and Furutani does not cure this deficiency as Furutani does not

teach or suggest the presently claimed expression vector. Accordingly, even if the teachings of Fersht and Furutani et al. were combined, the present invention would not be observed. However, this is not persuasive as applicants are arguing the references piecemeal. The rejection is a 103 in which the Office has acknowledged that neither reference teaches all elements of the instant claims alone. However, the combined disclosures of the cited the references do teach all elements of the instant claims and thus do provide an *prima facie* case of obviousness. The only element of the instant claims missing from the disclosure of Fersht is a sequence encoding an archaeobacterial FKBP-type PPIase. This element is clearly taught by Furutani et al. and thus Furutani et al. does in fact cure the deficiencies of Fersht. Applicants have presented no reasons why given the clear indication by Fersht that any chaperone fragment which possesses the ability to promote the folding of a polypeptide *in vivo* or *in vitro* can be used in the disclosed vectors and the disclosure by Furutani that the PPIase from *Methanococcus thermolithotrophicus* has molecular chaperone activity one of ordinary skill in the art would not have understood that the chaperone fragments of Fersht could be replaced with the PPIase from *Methanococcus thermolithotrophicus* disclosed by Furutani et al.

With regard to the 1.132 Declaration of Dr. Ideno previously submitted, applicants argue that the showing of unexpected results is commensurate with the scope of the presently claimed invention because TcFKBP18 used in the TcFK fusion 2 system is an archebacterial FKBP-type PPIase. In addition, applicants argue that a supplemental declaration shows that TcFKBP 18 is representative of the claimed archaeobacterial FKBP-type PPIase, since any archaeobacterial FKBP-type PPIase can show unexpectedly superior results because the PPIase has an IF domain and/or C-terminal domain. However, this is not persuasive as there is no evidence in the art, the specification and/or in the declaration that shows that the unexpected results are due to the presence of an IF domain in the chaperone fragment and clearly it cannot correlate to the presence of a C-terminal domain as the TcFKBP18 used in the TcFK fusion 2 system is an short-type archaeobacterial FKBP-type PPIase and thus lacks a C-terminal domain also. Thus the declaration merely presents an unsupported opinion and is insufficient to overcome the *prima facie* case of obviousness. As such the rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this

action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652